IN THE CLAIMS

Please amend claims 1 - 54, as follows:

1. (Original) An antiretroviral pharmaceutical composition comprising a selective combination of

i. a controlled release formulation comprising :

a. lamivudine or a pharmaceutically acceptable derivative thereof,

b. zidovudine or a pharmaceutically acceptable derivative thereof, and

c. a mixture of hydrophilic polymers, said polymers being selected from the group consisting of cellulose ethers, polyuronic acids and pharmaceutically acceptable gums or mixtures thereof and

d. a pharmaceutically acceptable calcium salt

ii. an immediate release formulation comprising at least one selective Non-nucleoside Reverse Transcriptase Inhibitors (NNRTI) drug or a pharmaceutically acceptable derivative thereof along with pharmaceutically acceptable excipients.

2. (Original) An antiretroviral pharmaceutical composition as claimed in claim 1 wherein said NNRTI drug is selected from nevirapine, and efavirenz.

3. (Original) An antiretroviral pharmaceutical composition as claimed in claim 1 which is in the form of two separate layers of said controlled release and the immediate release formulation

4. (Original) An antiretroviral pharmaceutical composition as claimed in claim 1 which is in the form of a core of said controlled release formulation and an outer coat of the immediate release formulation.

5. (Original) An antiretroviral pharmaceutical composition as claimed in claim 1 comprising a bilayer selective combination of

i. a first layer of controlled release formulation comprising :

a. lamivudine or a pharmaceutically acceptable derivative thereof,

b. zidovudine or a pharmaceutically acceptable derivative thereof, and

c. a mixture of hydrophilic polymers, said polymers being selected from the group consisting of cellulose ethers, polyuronic acids and pharmaceutically acceptable gums or mixtures thereof and

d. a pharmaceutically acceptable calcium salt

ii. a second layer of an immediate release formulation wherein said NNRTI is nevirapine or a pharmaceutically acceptable derivative thereof along with pharmaceutically acceptable excipients.

6. (Original) An antiretroviral pharmaceutical composition as claimed in claim 1 comprising a selective combination of

i. a core having a controlled release formulation comprising:

a. lamivudine or a pharmaceutically acceptable derivative thereof,

b. zidovudine or a pharmaceutically acceptable derivative thereof, and

c. a mixture of hydrophilic polymers, said polymers being selected from the group consisting of cellulose ethers, polyuronic acids and pharmaceutically acceptable gums or mixtures thereof and

d. a pharmaceutically acceptable calcium salt

ii. an outer coat of an immediate release formulation wherein said NNRTI is nevirapine or a pharmaceutically acceptable derivative thereof and pharmaceutically acceptable excipients.

7. (Original) An antiretroviral pharmaceutical composition as claimed in claim 1 comprising a selective bilayer combination of

i. a first layer of a controlled release formulation comprising :

a. lamivudine or a pharmaceutically acceptable derivative thereof,

b. zidovudine or a pharmaceutically acceptable derivative thereof, and

c. a mixture of hydrophilic polymers, said polymers being selected from the group consisting of cellulose ethers, polyuronic acids and pharmaceutically acceptable gums or mixtures thereof and

d. a pharmaceutically acceptable calcium salt

ii. a second layer of an immediate release formulation wherein said NNRTI is efavirenz or a pharmaceutically acceptable derivative thereof along with pharmaceutically acceptable excipients.

8. (Original) An antiretroviral pharmaceutical composition as claimed in claim 1 comprising a selective combination of

i. a core of controlled release formulation comprising :

a. lamivudine or a pharmaceutically acceptable derivative thereof,

b. zidovudine or a pharmaceutically acceptable derivative thereof, and

c. a mixture of hydrophilic polymers, said polymers being selected from the group consisting of cellulose ethers, polyuronic acids and pharmaceutically acceptable gums or mixtures thereof and

d. a pharmaceutically acceptable calcium salt

ii. an outer coat of an immediate release formulation wherein said NNRTI is efavirenz or a pharmaceutically acceptable derivative thereof along with pharmaceutically acceptable excipients.

9. (Currently Amended) The composition as claimed in ~~anyone of claims 1 to 8~~ claim 1 wherein the amount of lamivudine or pharmaceutically acceptable derivative thereof is from about 50 mg to about 500 mg.

10. (Original) The composition as claimed in claim 9 wherein the amount of lamivudine or pharmaceutically acceptable derivative thereof is about 300 mg.

11. (Currently Amended) The composition as claimed in ~~anyone of claims 1 to 8~~ claim 1 wherein the amount of zidovudine or pharmaceutically acceptable derivative thereof is from about 100 mg to about 1000 mg.

12. (Original) The composition as claimed in claim 11 wherein the amount of zidovudine or pharmaceutically acceptable derivative thereof is 600 mg.

13. (Currently Amended) The composition as claimed in ~~anyone of claims 1 to 12~~ claim 2 wherein the amount of nevirapine/efavirenz or pharmaceutically acceptable derivative thereof is from about 100 mg to about 1000 mg.

14. (Original) The composition as claimed in claim 13 wherein the amount of nevirapine or pharmaceutically acceptable derivative thereof is about 400 mg.

15. (Original) The composition as claimed in claim 13 wherein the amount of efavirenz or pharmaceutically acceptable derivative thereof is about 600 mg.

16. (Original) A composition as claimed in ~~anyone of claims 1 to 15~~ claim 1 wherein the cellulose ether is selected from amongst hydroxypropyl cellulose, hydoxypropyl methylcellulose, carboxy methylcellulose, sodium

carboxymethylcellulose, ethyl cellulose, methyl cellulose, hydroxy ethyl cellulose and the like.

17. (Original) A composition as claimed in claim 16 wherein the cellulose ether is hydroxypropyl methylcellulose and is present in an amount from about 2% to about 12% by weight of the controlled release formulation.

18. (Original) A composition as claimed in claim 17 wherein the cellulose ether is hydroxypropyl methylcellulose and is present in an amount from about 3% to about 8% by weight of the controlled release formulation.

19. (Currently Amended) A composition as claimed in ~~anyone of claims 1 to 18~~ claim 1 wherein the polyuronic acid is selected from amongst alginic acid, sodium alginate, calcium alginate, sodium calcium alginate, potassium alginate, ammonium alginate, magnesium alginate and the like.

20. (Original) A composition as claimed in claim 19 wherein the polyuronic acid is sodium alginate and is present in an amount from about 0.5% to about 10% by weight of the controlled release formulation.

21. (Original) A composition as claimed in claim 20 wherein the polyuronic acid is sodium alginate and is present in an amount from about 1 % to about 6% by weight of the controlled release formulation.

22. (Currently Amended) A composition as claimed in ~~anyone of claims 1 to 21~~ claim 1 wherein the pharmaceutically acceptable gum is selected from amongst guar gum, xanthan gum, gum karaya, tragacanth gum, gum acacia and the like.

23. (Original) A composition as claimed in claim 22 wherein the pharmaceutically acceptable gum is guar gum and is present in an amount from about 0. 1 % to about 10% by weight of the controlled release formulation.

24. (Original) A composition as claimed in claim 23 wherein the pharmaceutically acceptable gum is guar gum and is present in an amount from about 0.5% to about 6% by weight of the controlled release formulation.

25. (Currently Amended) The composition as claimed in ~~anyone of claims 1 to 24~~ claim 1 wherein the pharmaceutically acceptable calcium salt is selected from the group consisting of calcium sulphate, calcium phosphate, calcium carbonate and calcium chloride.

26. (Original) A composition as claimed in claim 25 wherein the pharmaceutically acceptable calcium salt is calcium sulphate and is present in an amount from about 0. 1 % to about 2.5% by weight of the controlled release formulation.

27. (Original) A composition as claimed in claim 26 wherein the pharmaceutically acceptable calcium salt is calcium sulphate and is present in an amount from about 0.1% to about 2% by weight of the controlled release formulation.

28. (Currently Amended) The composition as claimed in ~~anyone of claims 1 to 27~~ claim 1 wherein the controlled release formulation further comprises at least one water dispersible or water soluble diluent selected from amongst microcrystalline cellulose, dicalcium phosphate, calcium carbonate, lactose, powdered cellulose, starch, mannitol and the like.

29. (Original) The composition as claimed in claim 28 wherein the diluent is present from about 1 % to about 28% by weight of the controlled release formulation.

30. (Original) The composition as claimed in claim 29 wherein the diluent is microcrystalline cellulose.

31. (Original) The composition as claimed in claim 30 wherein the amount of microcrystalline cellulose is from about 5% to about 20% by weight.

32. (Original) The composition as claimed in claim 29 wherein the diluent is dicalcium phosphate.

33. (Original) The composition as claimed in claim 32 wherein the amount of dicalcium phosphate is from about 1% to about 5% by weight.

34. (Currently Amended) The composition as claimed in ~~anyone of claims 1 to 33~~ claim 1 wherein the controlled release formulation further comprises at least one lubricant selected from amongst magnesium stearate, calcium stearate, stearic acid, silicon dioxide, talc and the like.

35. (Original) The composition as claimed in claim 34 wherein the lubricant is present from about 0.1%-3% by weight.

36. (Currently Amended) The composition as claimed in ~~anyone of claims 1 to 35~~ claim 1 wherein the immediate release formulation comprises from about 10% to about 95% by weight of nevirapine or a pharmaceutically acceptable derivative

thereof along with one or more pharmaceutically acceptable excipients selected from amongst diluents, binders, disintegrants, lubricants, coloring agents and the like.

37. (Original) A composition as claimed in claim 36 wherein the diluent is selected from amongst microcrystalline cellulose, dicalcium phosphate, calcium carbonate, lactose, powdered cellulose, starch, mannitol and the like.

38. (Original) A composition as claimed in claim 37 wherein the diluent is powdered cellulose and is present in an amount from about 2% to about 15% by weight of the immediate release formulation.

39. (Original) A composition as claimed in claim 36 wherein the binder is selected from amongst carboxymethylcellulose sodium, povidone, pregelatinised starch, gelatin or mixtures thereof.

40. (Original) A composition as claimed in claim 39 wherein the binder is present in an amount from about 1% to about 10% by weight of the immediate release formulation

41. (Original) A composition as claimed in claim 36 wherein the disintegrant is selected from amongst crospovidone, sodium starch glycolate,

pregelatinised starch, carboxymethylcellulose sodium, croscarmellose sodium, starch and mixtures thereof.

42. (Original) A composition as claimed in claim 41 wherein the disintegrant is present in an amount from about 0.5% to about 15% by weight of the immediate release formulation.

43. (Original) The composition as claimed in claim 36 wherein the lubricant is selected from amongst magnesium stearate, calcium stearate, stearic acid, silicon dioxide, talc and the like.

44. (Original) The composition as claimed in claim 43 wherein the lubricant is present from about 0.1%-3% by weight.

45. (Original) A process for the preparation of an antiretroviral pharmaceutical composition comprising

(i) providing a controlled release formulation by mixing together active ingredients selected from amongst lamivudine, zidovudine or mixtures thereof with hydrophilic polymers selected from amongst cellulose ethers, polyuronic acids, pharmaceutically acceptable gums or mixtures thereof, and with a pharmaceutically acceptable calcium salt, optionally a diluent and a lubricant,

(ii) blending an immediate release formulation obtained of at least the NNRTI is blended with pharmaceutically acceptable excipients and

(iii) obtaining the composition therefrom by compressing the resulting blends into bilayered tablets.

46. (Original) A process for the preparation of an antiretroviral pharmaceutical composition comprising

(i) providing a core of said controlled release formulation by mixing together active ingredients selected from amongst lamivudine, zidovudine or mixtures thereof with hydrophilic polymers selected from amongst cellulose ethers, polyuronic acids, pharmaceutically acceptable gums or mixtures thereof, and with a pharmaceutically acceptable calcium salt, optionally a diluent and a lubricant,

(ii) providing an outer coat of an immediate release formulation obtained of at least the NNRTI selected from Nevirapine, and Efavirenz blended with pharmaceutically acceptable excipients and

(iii) obtaining the composition therefrom by applying the said outer coat over the said core by compression coating.

47. (Currently Amended) A process as described in claim 45 ~~45 or 46~~ wherein each blend is dry granulated prior to compression.

48. (Currently Amended) A process as described in claim 45 ~~45 or 46~~ wherein each blend is wet granulated prior to compression.

49. (Original) A method of reducing the pill burden in a patient suffering from HIV infection and/or Acquired Immunodeffieciency Syndrome by administering a three drug antiretroviral pharmaceutical composition which comprises of a combination of lamivudine and zidovudine as a controlled release component and nevirapine or efavirenz as an immediate release component.

50. (Original) A method of reducing the pill burden in a patient suffering from HIV infection and/or Acquired Immunodeficiency Syndrome by administering a three drug antiretroviral composition which comprises of Lamivudine and Zidovudine as a controlled release component and nevirapine or efavirenz as an immediate release component wherein the composition upon administration to the said patient provides a C_{max} of about 1.2 to 2.0 mcg/ml for Lamivudine, about 1.0 to 2.0 mcg/ml for Zidovudine and about 4.5 to 5.5 mcg/ml for Nevirapine.

51. (Original) A method of reducing the pill burden in a patient suffering from HIV infection and/or Acquired Immunodefficiency Syndrome by administering a three drug antiretroviral composition which comprises of Lamivudine and Zidovudine as a controlled release component and nevirapine or efavirenz as an immediate release

component wherein the composition upon administration to the said patient provides a AUC_{o-t} of about 8 to 14 mcg.hr/ml for Lamivudine, about 5 to 9 mcg.hr/ml for Zidovudine and about 32 to 40 mcg.hr/ml for Nevirapine.

52. (Original) A method of increasing the in vivo half life of Lamivudine and Zidovudine while not affecting the half life of Nevirapine and thus reducing the pill burden in a patient suffering from HIV infection and/or Acquired Immunodefficiency Syndrome by administering a three drug antiretroviral composition which comprises of Lamivudine and Zidovudine as a controlled release component and nevirapine or efavirenz as an immediate release component.

53. (Original) The method of Claim 51 wherein the composition upon administration to the said patient provides a $t_{1/2}$ of about 5 hrs for Lamivudine, about 2 hrs for Zidovudine and about 29 hrs for Nevirapine.

54. (Original) A method of reducing the pill burden in a patient suffering from HIV infection and/or Acquired Immunodefficiency Syndrome by administering a three drug antiretroviral composition which comprises of Lamivudine and Zidovudine as a controlled release component and nevirapine or efavirenz as an immediate release component wherein the composition upon administration to the said patient provides a C_{max} of the said drugs in the controlled release component which is substantially

similar to that provided by immediate release compositions of the said drugs when taken simultaneously, sequentially or concurrently.

55. (New) A process as described in claim 46 wherein each blend is dry granulated prior to compression.

56. (New) A process as described in claim 46 wherein each blend is wet granulated prior to compression.